

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

*DPM*  
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[Docket No. 2004N-0063]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Registration of Cosmetic Product Establishments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910–0027)—Extension**

The Federal Food, Drug, and Cosmetic Act (the act) provides FDA with the responsibility for assuring consumers that cosmetic products in the United States are safe and properly labeled. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA has developed the Voluntary Cosmetic Registration Program (VCRP). In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled “Registration of Cosmetic Product Establishment.” Form FDA 2511 is available on FDA’s VCRP Web site at <http://www.cfsan.fda.gov/acrobat/frm2511.pdf>.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

In the **Federal Register** of February 27, 2004 (69 FR 9339), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	15	1	15	0.4	6

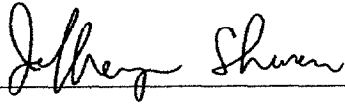
<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The VCRP was suspended during fiscal year (FY) 1998 due to a lack of budgetary funding and was reinstated at the beginning of FY 1999. The estimated hour burden for this information collection is 30 percent of the

previous level reported in 2000. In general, the larger cosmetic companies have resumed participating in the VCRP, whereas the smaller companies are lagging.

Dated: 7-13-04

July 13, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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